

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on October 23, 2009 is acknowledged. Applicant has cancelled claims 1-66. Claims 67-79 are now pending. It is noted that during the interview conducted on November 10, 2009, Applicant was requested to provide copies of the slide show presented. However, no such submission has been received.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on October 23, 2009 and January 27, 2010 is acknowledged. A signed copy is attached to this office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

The rejection of claims 50-55, 60, and 62-66 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicants cancellation of the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 50 and 60, 62-63 under 35 U.S.C. 102(b) as being anticipated by Bastart. (US Patent 5,698,582) has been withdrawn in view of Applicants cancellation of the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 50, 60, and 62-63 under 35 U.S.C. 103(a) as being unpatentable over Chi et al. (US 2003/0158249) has been withdrawn in view of Applicants cancellation of the claims.

The rejection of claims 51-55 under 35 U.S.C. 103(a) as being unpatentable over Bastart (US Patent 5,698,582) in view of Sharma et al. (US 2004/0116720) has been withdrawn in view of Applicants cancellation of the claims.

The rejection of claims 64-66 under 35 U.S.C. 103(a) as being unpatentable over Bastart (US Patent 5,698,582) in view of Zeldis et al. (US Patent 7,435,726) has been withdrawn in view of Applicants cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 80-81 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hausheer et al. (US Patent 6,040,330).

Hausheer discloses pharmaceutical formulation of a taxane antineoplastic agent, particularly paclitaxil or docetaxel or a pharmaceutically acceptable salt thereof, And N-methylpyrrolidin-2-one (NMP). The formulation also comprises additional solvents and excipients (abstract). Hausheer additionally discloses docetaxel is very poor soluble in

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water and the most preferred solvent used to dissolve docetaxel is polysorbate 80 (column 2, lines 24-28). pH controllers are also employed. Table 2 discloses citric acid.

Hausheer discloses the docetaxel is sold by the trade name Taxotere, which is anhydrous docetaxel with a water content of approximately 0.1%.

Hausheer does not disclose the specific pH of the final composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have adjusted the pH of the final composition of Haussher to a pH that is suitable for IV infusion which is routinely adjusted to be physiologically acceptable.

Claims 80-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Bastart. (US Patent 5,698,582) in view of Zeldis et al. (US Patent 7,435,726).

Bastart discloses compositions containing taxane derivatives, consisting of solutions of such derivatives in a surfactant. The solutions are used to prepare perfusion solutions (abstract).

Taxol and Taxotere are disclosed as known derivatives encompassed by the general formula disclosed in column 1 (column 2, lines 1-3). Taxol and Taxotere are paclitaxel and docetaxel, respectively. The compounds can be dissolved in a surfactant, such as polysorbate (column 2, lines 53-56). Polysorbate 80 is disclosed (Examples). The stock solution may be prepared by dissolving the active principle in ethanol, and then gradually add the surfactant. The ethanol is then completely or almost completely removed (column 3, lines 5-10).

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Paclitaxel and Docetaxel generically are known to be anhydrous compounds.

It is further noted that the claim recites the anhydrous docetaxel has had all alcohol removed, not the entire formulation be alcohol free. Therefore, the teachings of Bastart meet the limitations of the instant claims.

Bastart does not disclose the specific pH of the final composition or the pH agents used to achieve a specific pH.

Zeldis discloses injectable solutions of anticancer drugs, including taxotere d taxi. Zeldis discloses the addition of antioxidants such as ascorbic acid to the injectable formulations in order to reduce the rate by which the active ingredient will decompose (column 21, lines 4-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated an antioxidant into the vehicle in order to reduce the rate of drug decomposition as disclosed by the art of Zeldis.

Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have adjusted the pH of the final composition of Bastart to a pH that is suitable for IV infusion which is routinely adjusted to be physiologically acceptable.

Allowable Subject Matter

Claims 67-79 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615